

## **REMARKS**

Applicant respectfully requests entry of the Amendment and reconsideration of the claims.

Applicant has amended claim 1 and claim 17. Support for the amendments can be found throughout the specification, including at p. 7, lines 19-21. Applicant has also added new claim 29. Support for new claim 29 can be found throughout the specification, including at p. 6, lines 16-24; page 7, lines 6-16; page 10, line 31 to page 11, line 2; page 12, line 26 to page 13, line 8 and lines 25-34 .

Applicant respectfully requests reconsideration and withdrawal of the pending rejections under 35 U.S.C. § 103(a) and § 112, second paragraph.

### **Rejections under 35 U.S.C. § 112, second paragraph**

The Examiner rejects claims 1-22 [sic] under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. In claim 1, the Examiner rejects the claim in particular over the recitation of “determining whether a subject suffered...” This rejection is now moot since Applicant amended claim 1 and does not include this recitation.

The Examiner also rejects claim 17 for the recitation of “wherein the injury results in stroke.” The Examiner has interpreted the claim as “wherein the injury results from a stroke.” To expedite prosecute, Applicant has amended claim 17 to address the Examiner’s interpretation.

In view of the foregoing, Applicant respectfully requests removal of the rejections under 35 U.S.C. § 112, second paragraph.

### **Rejections under 35 U.S.C. § 103(a)**

Claims 1-5, 7-20, and 22 are rejected under 35 U.S.C. § 103(a) as allegedly obvious over U.S. Patent No. 6,046,187 (Berde et al.) in view of EP 100673 (Stracher) as evidenced by Matsunari et al. (Circulation, 2000) and Rosen et al. (Stroke, 1998). Claim 21 is rejected under 35 U.S.C. § 103(a) as allegedly obvious over U.S. Patent No. 6,046,187 in view of EP 100673 as evidenced by Matsunari et al. and Rosen et al. as applied above, and in further view of Young et al. (Current Treatment for Human Spinal Cord Injury).

To establish a *prima facie* case of obviousness, the teachings of the prior art should have suggested the claimed subject matter to the person of ordinary skill in the art, and all the claim limitations must be taught or suggested in the references cited by the Examiner. *In re Kotzab*, 217 F.3d 1365, 1370 (Fed. Cir. 2000). As articulated by the Supreme Court, a combination is obvious if it is no more than the predictable use of known elements according to their established functions; and there was a reason to combine the known elements. *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. \_\_\_, 127 S. Ct. 1727 (2007). To make a *prima facie* case of obviousness, "it remains necessary to identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed." *Id.* Applicant respectfully asserts that the combination of known elements was not obvious according to their established function and there was no motivation to combine the elements.

The Examiner cites the '187 patent (Berde et al.) for teaching the use of methylpredisone and procaine for the treatment of pain cause by nerve damage. The Examiner further cites EP 0100673 (Stracher et al.) for teaching the administration of leupeptin for the treatment of nerve damage. From this, the Examiner contends both patents teach the treatment of nerve damage and thereby further contends that methylpredisone, procaine, and leupeptin can all be combined since they all treat nerve damage.

Although both references teach the treatment of nerve damage, each references teaches a treatment through different mechanisms that do not lead to being combined. "A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. MPEP § 2141.02(VI); *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984).

Berde et al. teaches a local anesthetic agent (e.g., procaine, lidocaine, etc.) and a glucocorticosteroid that reactivates and/or prolongs a local anesthesia (col. 2, lines 52-54). The treatment of the nerve damage is to provide local anesthesia, thereby numbing the nerve(s) that is damaged. Stracher et al. disclose administering leupeptin to enhance neurofiber regrowth (see, e.g., p. 3, lines 23-28 and p. 5, lines 5-19). Local anesthetics suppress nerve growth (Takatori et al., *Anesth. Analg.* 102: 462-467 (2006)). Thus, one of skill in the art would not look to combine a local anesthetic (e.g., procaine) with a treatment that promotes nerve growth (e.g., leupeptin). In view of the Takatori et al. reference, a combination of local anesthetic and leupeptin would not work. For at least this reason, Applicants respectfully assert that one of ordinary skill in the

art would not combine a local anesthetic with leupeptin to treat nerve damage. Due to the difference in mechanism of treatment, there is no motivation to combine the references.

In view of the foregoing, Applicant respectfully requests reconsideration and withdrawal of the rejections under 35 U.S.C. § 103(a).

**Summary**

For the reasons set forth above, the applicant believes that all of the pending rejections have been adequately addressed and that the present claims are in condition for allowance, which action is respectfully requested. The Examiner is invited and encouraged to contact the undersigned directly if such contact will expedite the prosecution of this application to issue.

Respectfully submitted,

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